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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/782,702 | 02/19/2004 | Shlomo Gabbay | SHE-6933 | 5568 |
| 26294 | 7590 | 06/13/2006 | EXAMINER | |
| TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114 | | | STEWART, ALVIN J | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3738 | | |

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|------------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/782,702 | GABBAY, SHLOMO | |
| | Examiner Alvin J. Stewart | Art Unit 3738 | |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | | |
| Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. | | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). | | | |
| <p>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p> | | | |
| Status | | | |
| <p>1)<input type="checkbox"/> Responsive to communication(s) filed on _____.</p> <p>2a)<input type="checkbox"/> This action is FINAL. 2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p> | | | |
| Disposition of Claims | | | |
| <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1-22</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1-3,8-16,21 and 22</u> is/are rejected.</p> <p>7)<input checked="" type="checkbox"/> Claim(s) <u>4-7 and 17-20</u> is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p> | | | |
| Application Papers | | | |
| <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input checked="" type="checkbox"/> The drawing(s) filed on <u>19 February 2006</u> is/are: a)<input checked="" type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p style="margin-left: 20px;">Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</p> <p>11)<input type="checkbox"/> The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</p> | | | |
| Priority under 35 U.S.C. § 119 | | | |
| <p>12)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p style="margin-left: 20px;">1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p style="margin-left: 20px;">2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p style="margin-left: 20px;">3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> | | | |
| <p>* See the attached detailed Office action for a list of the certified copies not received.</p> | | | |
| Attachment(s) | | | |
| <p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>02/19/04</u>.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p> | | | |

Claim Objections

Claim 15 is objected to because of the following informalities: claim 15 is almost identical to claim 11. Please verify if correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-11, 13-15 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Reger US Patent 5,258,023.

Reger discloses a prosthetic heart valve (10) comprising a valve member (20) having a cylindrical sidewall portion, a support of a substantially flexible material (30), a strip of pliant material (104) around valve member intermediate an inflow end and outflow end of the valve member and a covering (30) over a radially outer exposed surface.

Regarding claims 8-11 and 14-15, see Figs. 21-22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reger US Patent 5,258,023.

Reger discloses the invention substantially as claimed. However, Reger does not disclose a strip made of natural material and synthetic material or biological tissue material. Additionally, Reger does not disclose a valve member made of homograft or xenograft and does not disclose a support having a radial thickness.

Regarding claims 2, 3 and 12, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the synthetic material of the Reger reference with the material properties of the Applicant's invention, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flexible material by having a thickness of less than about 0.5 mm, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

Claims 4-7 and 17-20 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER

Art Unit 3738

June 08, 2006.